

**LIBELED:** 8-14-59, E. Dist. N.Y.

**CHARGE:** 403(f)—while held for sale, the information required to appear on the label did not appear on the label in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since such information was not printed in the English language; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin content and its label failed to bear as required by regulations, a statement of the proportion of the minimum daily requirements of vitamin A, vitamin B<sub>1</sub>, vitamin C, vitamin D, riboflavin, or niacin or niacinamide supplied by a specified quantity of the food when consumed during a period of one day.

The libel alleged also that various drugs were adulterated and misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6043.

**DISPOSITION:** 1-8-60. Default—destruction.

**26736. Iodine preparation.** (F.D.C. No. 43937. S. No. 77-694 P.)

**QUANTITY:** 2 5-gal. containers and 1 fluid oz. btl. at Cleveland, Ohio, in possession of Inorganic Bioelements, Inc.

**SHIPPED:** 3-6-59 and 8-27-59, from Oak Ridge, Tenn., by Martin Anderson Co.

**LABEL IN PART:** (5-gal. containers) "Amidal An Iodine Preparation Active Ingredients: Edible Proteins consisting of Gelatin, Extract of Algae and Pepsin, and 5% of Iodine in the form of Sodium Compounds, including Sodium Iodide, Sodium Iodate, and Sodium Hypiodite. Indicated as a source of iodine for nutritional purposes and for the prevention of goiter, in animals. Directions: \* \* \*  $\frac{1}{2}$  Fluid Gallon Distributed By Inorganic Bioelements, Inc. \* \* \* Cleveland 10, Ohio"; and (btl.) "Amio 5% Nutritional Iodine Preparation for Human Use \* \* \* Inorganic Bioelements, Inc., Cleveland 10, Ohio Distributor."

**ACCOMPANYING LABELING:** Literature and leaflets entitled "The Importance of Iodine in the Nutrition of Farm Animals," and "The Importance of Iodine in Nutrition" and a number of loose "Amio" and "Amidal" labels.

**RESULTS OF INVESTIGATION:** Analysis showed that the article of (5-gal. containers) contained 1.42 percent free iodine and a total iodine content of 5.20 percent, and (btl.) 0.68 percent free iodine and a total iodine content of 5.82 percent. The bottle was repacked and labeled by the dealer from the 5-gal. containers shipped as described above.

**LIBELED:** 12-4-59, N. Dist. Ohio.

**CHARGE:** 403(a)—when shipped and while held for sale, the label statement of the article (btl.) "5% Nutritional Iodine" and "One Drop of Amio contains 3.5 milligrams Iodine, equivalent to seven times the minimum daily requirement for adults and children," was false and misleading since the article contained more than 5 percent iodine and 3.5 milligrams iodine will supply 35 times the minimum daily requirement for iodine; and 403(e) (2)—the article (5-gal. container) failed to bear an accurate statement of the quantity of contents since the label statement " $\frac{1}{2}$  Fluid Gallon" was inaccurate.

The libel charged also that the article was misbranded under the provisions of the law applicable to drugs and devices as reported in notices of judgment on drugs and devices, No. 6060.

**DISPOSITION:** 1-18-60. Default—destruction.